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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/473,713	12/29/1999	GREGORY R.J. THATCHER	1995-033-12U	1352

7590  
Clark & Elbing LLP  
101 Federal Street  
Boston, MA 02110

07/29/2005

EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/473,713

Applicant(s)

THATCHER ET AL.

Examiner

Cybille Delacroix-Muirheid

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11,13-20,22,24,26,28,33-41 and 43 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 33-35, 37-40 is/are allowed.  
6) ☒ Claim(s) 11,13-20,22,24,26,28,36,41 and 43 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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***Detailed Action***

The following is responsive to applicant's amendment received April 28, 2005.

Claims 1-10, 12, 21, 23, 25, 27, 29-32, 42 are cancelled. Claims 11, 13-20, 22, 24, 26, 28, 33-41, 43 are currently pending.

The previous objection of claim 43, set forth in paragraph 1 of the office action mailed Jan. 26, 2005 is withdrawn in view of applicant's amendment and the remarks contained therein.

The following new ground(s) of rejection is submitted upon further consideration of the pending claims with a supervisory patent examiner.

The indication of allowability of claims 11, 13, 14-20, 22, 24, 26, 28, 36, 41 is withdrawn in view of the following new ground(s) of rejection.

***New Ground(s) of Rejection***

***Claim Rejection(s)—35 USC 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

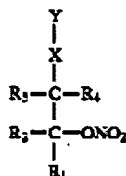
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 11, 13, 14-20, 22, 24, 26, 28, 36, 41 and 43 are rejected under 35 U.S.C. 102(a) as being anticipated by Thatcher et al., 5,807,847 (already of record).

Thatcher et al. teach a method of effecting "tissue relaxation" in a patient in need thereof, the method comprising administering an effective amount of a pharmaceutical

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composition containing an aliphatic nitrate ester compound represented by the general formula (col. 3)



where X is CH<sub>2</sub>, O, NH, NMe, S, SO<sub>2</sub>M, PO<sub>2</sub>HM, PO<sub>2</sub>M<sub>2</sub>, SH, SR<sub>7</sub>, P(O)(OR<sub>7</sub>)(OR), P(O)(OR<sub>7</sub>)(OM), P(O)(OR<sub>7</sub>)(R<sub>8</sub>), P(O)(OM)R<sub>8</sub>, SO<sub>2</sub>M, S(O)R<sub>8</sub>, S(O)<sub>2</sub>R<sub>8</sub>, S(O)OR<sub>8</sub> or S(O)<sub>2</sub>OR;

Y is zero, SR<sub>4</sub>, SR<sub>10</sub>, SSR<sub>10</sub>, SO<sub>2</sub>M, SO<sub>2</sub>M, PO<sub>2</sub>HM, PO<sub>2</sub>M<sub>2</sub>, P(O)(OR<sub>7</sub>)(OM), or P(O)(OR<sub>7</sub>)OR<sub>8</sub>;

R<sub>5</sub>, R<sub>6</sub>, R<sub>8</sub>, R<sub>9</sub>, R<sub>10</sub> are the same or different alkyls containing 1-12 carbon atoms or C<sub>1</sub> or C<sub>2</sub> connections to R<sub>1</sub> or R<sub>3</sub> in cyclic derivatives;

R<sub>7</sub> is C<sub>1</sub>-C<sub>9</sub> alkyl or acyl;

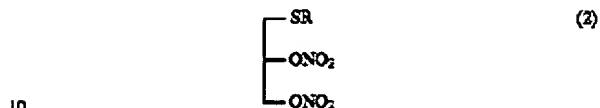
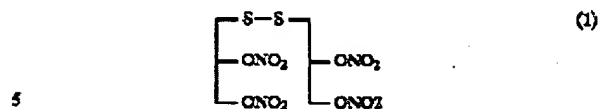
R<sub>2</sub> and R<sub>4</sub> are the same or different and selected from H, ONO<sub>2</sub>, C<sub>1</sub>-C<sub>4</sub> alkyl optionally bearing 1-3 nitrate groups, and acyl groups (-C(O)R<sub>10</sub>);

R<sub>1</sub> and R<sub>3</sub> are the same or different and selected from H, C<sub>1</sub>-C<sub>4</sub> alkyl and chains, which may include one O, linking R<sub>1</sub> and R<sub>3</sub> to form pentosyl, hexosyl, cyclopentyl or cyclohexyl rings, which rings optionally bear hydroxyl substituents; and

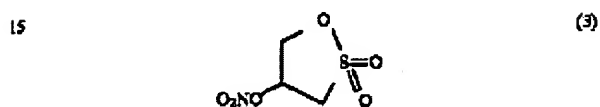
M is H, Na<sup>+</sup>, K<sup>+</sup>, NH<sub>4</sub><sup>+</sup> or NH<sub>n</sub>R<sub>n(4-n)</sub>, where n is 0-3.

Species exemplified by Thatcher et al. comprise the following compounds,

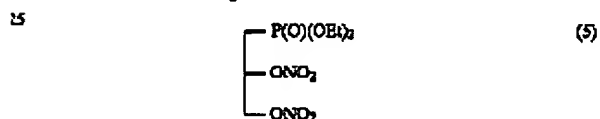
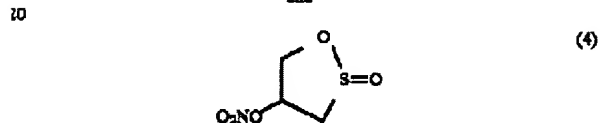
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where R is  $\text{SO}_3\text{M}$   
and M is  $\text{Na}^+$  or  $\text{K}^+$



and



Please see col. 4.

The claims are anticipated by Thatcher et al. because Thatcher et al. disclose administering of identical active agents to a subject in need thereof using the claimed method steps. Therefore, sedation or mitigation of anxiety would be inherent. Moreover, the patient population being treated in the claims and prior art overlap.

### Conclusion

Claims 11, 13, 14-20, 22, 24, 26, 28, 36, 41 and 43 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybillie Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

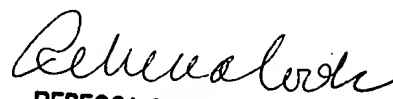
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM 

July 25, 2005

  
REBECCA COOK  
PRIMARY EXAMINER  
GROUP ~~1200~~ 1614